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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/016,706      | 12/11/2001  | Cinderella Blanchat  | 7594-84862          | 4431             |

7590

12/12/2003

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EXAMINER

KRISHNAN, GANAPATHY

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1623

8

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/016,706

Applicant(s)

BLANCHAT ET AL.

Examiner

Ganapathy Krishnan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Amendment B (papers #7) filed September 22, 2003 has been received, entered into the record and carefully considered. The following information provided in the response affects the instant application:

1. Claims 1, 3, 5, 13-15 and 18-23 have been amended.
2. Remarks drawn to rejections under 35 U.S.C. 101 and 112 first, second paragraph.

Claims 1-23 are pending.

### ***Claim Objections***

Claim 3 is objected to because of the following informalities: The term "Factors" is misspelled at lines 3 and 4. Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-3 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 11 of U.S. Patent No. 6646120 ('120 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Claims 1 and 2 of the instant application is drawn to a composition comprising a dextran derivative of formula  $DMC_aB_bSu_cS_d$  wherein specific degrees of substitution are recited, and at least one growth factor. Dependent claim 3 recites the growth factors, which includes Fibroblast Growth Factor. Similar recitations are seen in claims 1, 6 and 11 of the '120 patent. The difference is Claim 11 of the '120 patent recites a medicine comprising the said dextran derivative and at least one additional active principle which is selected from an acidic or basic fibroblast growth factor. The other difference is that the degrees of substitution recited are slightly different but still overlapping. An overlap is also seen in the degrees of substitution recited in claims 2-5 of the '120 patent. The difference seen is instant claim 5 recites a biomaterial comprising dextran derivatives and several growth factors whereas claim 11 of the '120 patent recites at least one growth factor which means there could be several.

It would have been obvious to one of ordinary skill in the art that instant claims 1-3 and 5 are substantially overlapping, and identical in parts, to claims 1-6 and 11 of the '120 patent.

The composition of the instant application must contain new and non-obvious variations over the copending applications to be patentably distinct.

***Claim Rejections - 35 USC § 101***

Claims 20-22 are rejected under 35 U.S.C. 101 is being maintained because the claim recites using a solid biomaterial for the preparation of repair/filling material/implants/prostheses. The claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

The rejections of claims 14, 15 and 19 under 35 U.S.C. 112 second paragraph have been overcome by amendments to the claims. However, the rejections of claims 1-23 are being maintained for reasons of record.

Claim 1 still has limitations within parentheses. It is not clear if these limitations are part of the claim. If the limitations are part of the claim the parentheses have to be removed. If they are not part of the claim they have to be deleted. Also, the claim recites, "essentially comprises". It is not clear what this recitation means

Claims 13 and 18 recite, "copolymers of polyethylene glycol and of polylactide-co-glycolide". It is not clear if the term copolymers at line 3 means a copolymer formed between polyethylene glycol and polylactide-co-glycolide. Clarification is needed.

Claims 20-22 recite a process for preparing the biomaterial of claim 1 but does not set forth the steps for the said process. The claim also recites using the solid biomaterial for the preparation of implants, but does not set forth the method/process

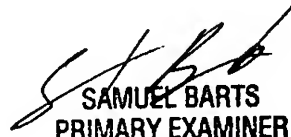
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steps involved. It is not clear what method/process steps the applicant's are intending to encompass in the said use of the solid biomaterial. The claim is indefinite.

Claims that depend from rejected base claims that are unclear/indefinite are also rendered unclear/indefinite.

***Conclusion***

1. Claims 1-23 are rejected.

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1600